

WHAT IS CLAIMED IS:

1. A gastrointestinal pacemaker device for pacing the gastrointestinal tract wall of a patient comprising:

5 a) an outer housing configured to be introduced into the gastrointestinal tract of a patient;

b) an inner cavity within the outer housing;

c) a pulse generator in the inner cavity for generating intermittent discharges to the gastrointestinal tract wall of the patient; and

d) a power source connected to the pulse generator.

10 2. The gastrointestinal pacemaker of claim 1, further comprising one or more than one electrode connected to the pulse generator, where the one or more than one electrode delivers the discharges from the pulse generator to the gastrointestinal tract wall.

3. The gastrointestinal pacemaker of claim 1, where the power source is a self-contained battery.

15 4. The gastrointestinal pacemaker of claim 1, where the power source is configured to receive energy from an external source.

5. The gastrointestinal pacemaker of claim 1, where the power source comprises a piezoelectric crystal.

20 6. The gastrointestinal pacemaker of claim 5, where the power source generates electrical activity by converting intrinsic gastrointestinal mechanical or physical activity to electrical power.

7. The gastrointestinal pacemaker of claim 1, further comprising:

a) a sensor for sensing gastrointestinal tract wall electrical activity; and

b) one or more than one microprocessor connecting the pulse generator to the sensor.

25 8. The gastrointestinal pacemaker of claim 7, where the pulse generator delivers discharges to the gastrointestinal tract wall that have an amplitude, duration, frequency, pattern or pulse width or combination of these parameters determined, at least in part, by the electrical

activity of the gastrointestinal tract sensed by the sensor.

9. The gastrointestinal pacemaker of claim 7, further comprising one or more than one electrode connected to the sensor, where the one or more than one electrode senses activity of the gastrointestinal tract wall.

5 10. The gastrointestinal pacemaker of claim 7, further comprising one or more than one electrode connected to the pulse generator for delivering the discharges from the pulse generator to the gastrointestinal tract wall, and to the sensor for sensing electrical activity of the gastrointestinal tract wall; and

 further comprising an electrode switching circuit to control the function and polarity of
10 the one or more than one electrode.

11. The gastrointestinal pacemaker of claim 1, further comprising a telemetry unit comprising a receiver and a transmitter.

12. The gastrointestinal pacemaker of claim 7, further comprising random access memory connected to one or more than one microprocessor.

15 13. The gastrointestinal pacemaker of claim 1, further comprising a gastrointestinal tract location sensor.

14. The gastrointestinal pacemaker of claim 1, where the outer housing is generally elliptical and has an axial length of between about 1.5 cm and 3 cm, and a midline diameter of between about 8 mm and 12 mm.

20 15. The gastrointestinal pacemaker of claim 2, where the one or more than one electrode is a plate attached to the outer housing.

16. The gastrointestinal pacemaker of claim 2, where the one or more than one electrode comprises a coiled flexible wire.

25 17. The gastrointestinal pacemaker of claim 9, where the one or more than one electrode is a plate attached to the outer housing.

18. The gastrointestinal pacemaker of claim 9, where the one or more than one electrode comprises a coiled flexible wire.

19. The gastrointestinal pacemaker of claim 1, further comprising one or more than one anchoring device to attach the gastrointestinal pacemaker to the gastrointestinal tract wall.

20. The gastrointestinal pacemaker of claim 19, where at least one of the one or more than one anchoring device comprises a piercing element for piercing the gastrointestinal tract wall.

21. The gastrointestinal pacemaker of claim 19, where at least one of the one or more than one anchoring device comprises means for applying suction to the gastrointestinal tract wall.

22. The gastrointestinal pacemaker of claim 19, where at least one of the one or more than one anchoring device comprises both a piercing element for piercing the gastrointestinal tract wall and means for applying suction to the gastrointestinal tract wall.

23. A method for affecting peristalsis or treating a disruption of peristalsis comprising:

a) selecting a patient having a need for altering peristalsis or having a disruption of peristalsis;

b) introducing a gastrointestinal pacemaker into the gastrointestinal tract of the patient; and

c) activating the gastrointestinal pacemaker to affect peristalsis.

24. The method of claim 23, further comprising removing the gastrointestinal pacemaker.

25. The method of claim 23, where the gastrointestinal pacemaker further comprises one or more than one anchoring device; and

where the method further comprises activating the one or more than one anchoring device thereby anchoring the gastrointestinal pacemaker to the gastrointestinal tract wall.

26. The method of claim 23, where at least one of the one or more than one anchoring device comprises a piercing element for piercing the gastrointestinal tract wall; and

where activating the anchoring device comprises piercing the gastrointestinal tract wall with the piercing element.

27. The method of claim 23, where at least one of the one or more than one anchoring device comprises means for applying suction to the gastrointestinal tract wall; and

where activating the anchoring device comprises creating suction between the anchoring device and the gastrointestinal tract wall.

5 28. The method of claim 23, where at least one of the one or more than one anchoring device comprises both a piercing element for piercing the gastrointestinal tract wall, and means for applying suction to the gastrointestinal tract wall; and

 where activating the anchoring device comprises both piercing the gastrointestinal tract wall with the piercing element and creating suction between the anchoring device and the
10 gastrointestinal tract wall.

29. The method of claim 23, where introducing the gastrointestinal pacemaker into the gastrointestinal tract of the patient comprises having the patient swallow the gastrointestinal pacemaker, or placing the gastrointestinal pacemaker through the anus into the large intestine.

15 30. The method of claim 23, where introducing the gastrointestinal pacemaker into the gastrointestinal tract of a patient comprises using means for manipulating the gastrointestinal pacemaker.

31. The method of claim 23, further comprising supplying power to the gastrointestinal pacemaker using a power conduit connected to a power source external to the patient's gastrointestinal tract.

20 32. The method of claim 23, further comprising reintroducing the gastrointestinal pacemaker into the gastrointestinal tract of the patient and activating the reintroduced gastrointestinal pacemaker and activating the gastrointestinal pacemaker.

33. An anchoring device for a gastrointestinal pacemaker comprising:

25 a) a housing having a membrane or an opening at the distal end, and containing a piercing element having a proximal end and a distal end, a disk having a proximal side and a distal side, and an elastic structure surrounding the piercing element;

 b) a space adjoining the proximal side of the disk, where the space is in communication

with a pressure producing source; and

c) a valve between the pressure producing source and the space;

where the proximal end of the piercing element is attached to the distal side of the disk.

34. A method of anchoring a gastrointestinal pacemaker comprising:

5 a) providing a gastrointestinal pacemaker having an anchoring device according to claim 33;

b) introducing the gastrointestinal pacemaker into the gastrointestinal tract of a patient; and

10 c) causing the valve to travel to an activated position, thereby allowing the contents of the pressure producing source to exit the pressure producing source into the space on the proximal side of the disk, compressing the elastic structure and advancing the piercing element through the opening or membrane, and into the gastrointestinal tract wall of the patient.

15 35. The method of claim 34, further comprising detaching the anchor from the gastrointestinal tract wall comprising causing the valve to travel to a deactivated position, thereby allowing the elastic structure to force the disk back to its original pre-activation position withdrawing the piercing element from the gastrointestinal tract wall.

36. The method of claim 34, further comprising detaching the anchor from the gastrointestinal tract wall by detaching the piercing element from the gastrointestinal pacemaker entirely, thereby leaving the piercing element fixed to the gastrointestinal tract wall.

20 37. An anchoring device for a gastrointestinal pacemaker comprising:

a) a housing defining a space, and containing a proximal disk, a distal disk and a rod, connecting the proximal disk to the distal disk;

b) a circumferential partition separating the space into a proximal compartment and a distal compartment;

25 c) an elastic structure surrounding the rod between the circumferential partition and the proximal disk; and

d) a stop or stops to prevent the proximal disk from advancing distally into the distal

compartment;

where the proximal compartment comprises a first opening in communication externally and a second opening in communication with a pressure producing source;

where the second opening is also in contact externally when the anchoring device is not activated and in contact with the pressure producing source across a valve, during activation; and a conduit in the housing connecting the first opening with the distal compartment.

38. A method of anchoring a gastrointestinal pacemaker comprising:

a) providing a gastrointestinal pacemaker having an anchoring device according to claim 37;

b) introducing the gastrointestinal pacemaker into the gastrointestinal tract of a patient;

c) causing the valve to travel to an activated position allowing the contents of the pressure producing source to exit the pressure producing source and communicate with the proximal compartment by the second opening, while closing the communication external to the gastrointestinal pacemaker through the second opening, thereby causing the proximal disk to travel further into the proximal compartment and create suction between the distal disk and the gastrointestinal tract wall in contact with the distal disk.

39. The method of claim 38, further comprising detaching the anchor from the gastrointestinal tract wall comprising opening a valve in the conduit, thereby breaking suction between the distal disk and the gastrointestinal tract wall, causing the spring to translate the proximal disk to a deactivation position.

40. An anchoring device for a gastrointestinal pacemaker comprising:

a) a first section having a piercing element for reversibly piercing the gastrointestinal tract wall of a patient; and

b) a second section connected to the first section configured to create suction between the anchoring device and the gastrointestinal tract wall.

41. The anchoring device of claim 40, where the first section comprises:

a) a housing having a proximal end, and a distal end with an opening communicating

externally;

where the proximal end of the housing communicates either with a first opening by a conduit, or with the pressure producing source depending on the position of a valve between the conduit and the pressure producing source; and

- 5 b) a piercing element surrounded by an elastic structure within the housing having a proximal end attached to a disk, and a distal end aligned with the opening in the distal end of the housing.

42. A method of anchoring a gastrointestinal pacemaker comprising:

- 10 a) providing a gastrointestinal pacemaker having an anchoring device according to claim 41;
- b) introducing the gastrointestinal pacemaker into the gastrointestinal tract of a patient;
- c) creating suction between the second section and the gastrointestinal tract wall; and
- d) piercing the gastrointestinal tract wall with the piercing element of first section.

- 15 43. The method of claim 42, further comprising detaching the anchor from the gastrointestinal tract wall comprising removing the piercing element from the gastrointestinal tract wall and breaking the suction between the second section and the gastrointestinal tract wall.